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Peter Andersen

SSISAUSA

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EXAMINER

SWARTZ, RODNEY P

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Art Unit: 1645

DETAILED ACTION

1. Applicants' Response to Final Office Action, received 9 February 2009, is acknowledged. Claims 6-8 have been canceled. Claims 9, 12, 13, 16, 17, 24, 26 and 29 have been amended.
2. Claims 9, 10, 12, 13, 16, 17 and 24-29 are pending and under consideration.

Rejections Withdrawn or Moot

3. The rejection of claims 6-8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is moot in light of the cancellation of the claims.
4. The rejection of claim 29 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from a canceled claim is withdrawn in light of the amendment of the claim.
- 5.

Rejections Maintained

6. The rejection of claims 12, 13 and 28 under 35 U.S.C. 102(b) as being anticipated by Horwitz (U.S. Pat. No. 5,108,745), is maintained.

Applicants argue that Horwitz does not teach the claimed invention and submitted a Declaration pursuant to 37 CFR 1.132 by Peter Andersen, one of the named inventors on the instant application.

The examiner has considered applicants argument and the Declaration of Peter Andersen, but does not find them persuasive.

MPEP §716.07 recites: Inoperability of References

Since every patent is presumed valid (35 U.S.C. 282), and since that presumption includes the presumption of operability (Metropolitan Eng. Co. v. Coe, 78 F.2d 199, 25 USPQ 216 (D.C.Cir. 1935), examiners should not express any opinion on the operability of a patent. Affidavits or declarations attacking the operability of a patent cited as a reference must rebut the presumption of operability by a preponderance of the evidence. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980).

Further, since in a patent it is presumed that a process if used by one skilled in the art will produce the product or result described therein, such presumption is not overcome by a mere showing that it is possible to operate within the disclosure without obtaining the alleged product. In re Weber, 405 F.2d 1403, 160 USPQ 549 (CCPA 1969). It is to be presumed also that skilled workers would as a matter of course, if they do not

Art Unit: 1645

immediately obtain desired results, make certain experiments and adaptations, within the skill of the competent worker. The failures of experimenters who have no interest in succeeding should not be accorded great weight. In re Michalek, 162 F.2d 229, 74 USPQ 107 (CCPA 1947); In re Reid, 179 F.2d 998, 84 USPQ 478 (CCPA 1950). Where the affidavit or declaration presented asserts inoperability in features of the reference which are not relied upon, the reference is still effective as to other features which are operative. In re Shepherd, 172 F.2d 560, 80 USPQ 495 (CCPA 1949). Where the affidavit or declaration presented asserts that the reference relied upon is inoperative, the claims represented by applicant must distinguish from the alleged inoperative reference disclosure. In re Crosby, 157 F.2d 198, 71 USPQ 73 (CCPA 1946). See also In re Epstein, 32 F.3d 1559, 31 USPQ2d 1817 (Fed. Cir. 1994) (lack of diagrams, flow charts, and other details in the prior art references did not render them nonenabling in view of the fact that applicant's own specification failed to provide such detailed information, and that one skilled in the art would have known how to implement the features of the references).

If a patent teaches or suggests the claimed invention, an affidavit or declaration by patentee that he or she did not intend the disclosed invention to be used as claimed by applicant is immaterial. In re Pio, 217 F.2d 956, 104 USPQ 177 (CCPA 1954). Compare In re Yale, 434 F.2d 66, 168 USPQ 46 (CCPA 1970) (Correspondence from a co-author of a literature article confirming that the article misidentified a compound through a typographical error that would have been obvious to one of ordinary skill in the art was persuasive evidence that the erroneously typed compound was not put in the possession of the public.).

35 U.S.C. 282, recites: Presumption of validity; defences.

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. Notwithstanding the preceding sentence, if a claim to a composition of matter is held invalid and that claim was the basis of a determination of nonobviousness under section 103(b)(1), the process shall no longer be considered nonobvious solely on the basis of section 103(b)(1). The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity. The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

- (1) Noninfringement, absence of liability for infringement, or unenforceability,
- (2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability,
- (3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title,
- (4) Any other fact or act made a defense by this title.

In actions involving the validity or infringement of a patent the party asserting invalidity or noninfringement shall give notice in the pleadings or otherwise in writing to the adverse party at least thirty days before the trial, of the country, number, date, and name of the patentee of any patent, the title, date, and page numbers of any publication to be relied upon as anticipation of the patent in suit or, except in actions in the United States Court of Federal Claims, as showing the state of the art, and the name and address of any person who may be relied upon as the prior inventor or as having prior knowledge of or as having previously used or offered for sale the invention of the patent in suit. In the absence of such notice proof of the said matters may not be made at the trial except on such terms as the court requires.

Invalidity of the extension of a patent term or any portion thereof under section 154(b) or 156 of this title because of the material failure—

- (1) by the applicant for the extension, or
- (2) by the Director, to comply with the requirements of such section shall be a defense in any action involving the infringement of a patent during the period of the extension of its term and shall be pleaded. A due diligence determination under section 156(d)(2) is not subject to review in such an action.

Art Unit: 1645

Based upon these two recitations, the rejection is maintained because a patent shall be presumed valid and the declaration attacking the operability of the patent cited as a reference does not meet the criterion that the declaration "must rebut the presumption of operability by a preponderance of the evidence".

7. The rejection of claims 9, 10, 12, 13, 16, 17, and 24-27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is maintained.

Applicants argue that the amendment of the claims obviates the rejection because the claims now depend from claim 29.

The examiner has considered applicants' argument, but does not find it persuasive because: 1) the claims do not depend from claim 29, but claim 28; and, 2) the written description requirement rejection is drawn to the claimed "fragments thereof". Therefore, the claims continue to contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, i.e., vaccines comprising fragments of mycobacterial polypeptides.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly amended claim 29 depends from a rejected claim 28.

Art Unit: 1645

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1645

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 9, 2009